5. 510(K) SUMMARY

AUG 13 2008

Manna Omni International, Inc.

This summary was prepared on the 25th day of June in the year 2008 per 21 CFR 807.92. This 510(k) submission is for the MAX Adjusting Instrument owned by Manna Omni International, Inc., which is located at 340 E. Commonwealth Avenue in Fullerton, CA 92832. The submitter and primary contact is Stephen Tsai, who can be contacted by phone at 714-871-7118 or fax at 714-871-3372. The device is submitted for regulation under product code LXM of unclassified devices that are plunger-like joint manipulators and reviewed by the physical medicine panel.

(a)(2)	Device trade name	MAX Adjusting Instrument
	Common name	Chiropractic adjusting instrument
	Classification name	Manipulator, plunger-like joint
(a)(3)	Legally marketed devices for substantial equivalence	K080261 Impulse iQ Adjusting Instrument K072519 Activator V Spinal Adjusting Instrument K010851 Harrison Hand Held Adjusting Instrument
(a)(4)	Device description	MAX is a hand-held chiropractic adjusting instrument that features automatic battery-powered operation instead of manual thrust. The electromechanical instrument uses a plunger-like mechanism to deliver thrust for chiropractic adjustment. The instrument is intended for use by a health care professional licensed by the law of the state in which he or she practices.
(a)(5)	Intended Use	MAX is indicated for chiropractic adjustment of the spine and/or extremities. MAX should be used by a licensed health care professional only. Intended for external use only.
(a)(6)	Technological Characteristics	The MAX adjusting device delivers an automatic thrust from the push of a trigger by using a lithium ion rechargeable battery to power a solenoid. The energy source is a lithium-ion rechargeable battery. A manual switch allows the user to select single thrust or multiple thrust modes. The instrument has four force settings.
(b)(1)	Performance Data	MAX has four force settings that have been mechanically tested to deliver 75N, 125N, 175N, or 250N per thrust. The lithium-ion rechargeable battery has been tested for safety and performance.
(b)(3)	Conclusion	MAX is substantially equivalent to predicate devices in terms of safety, effectiveness, and performance. It uses a plunger-like mechanism for chiropractic adjustment of the spine and extremities and is intended for external use only. The device is only used by licensed health care professionals. MAX delivers a similar force range to predicate devices but uses a rechargeable battery to power the push-button, automatic thrust.

21 CFR 807.92

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2008

Manna Omni International, Inc.
% Stephen Tsai, M.D.
President
340 East Commonwealth Avenue
Fullerton, California 92832

Re: K082218
Trade/Device Name: MAX Adjusting Instrument
Regulatory Class: Unclassified
Product Code: LXM
Dated: August 4, 2008
Received: August 6, 2008

Dear Dr. Tsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082218

Manna Omni International, Inc.

4. INDICATIONS FOR USE STATEMENT

Indications for Use
MAX Adjusting Instrument

MAX is indicated for chiropractic adjustment of the spine and/or extremities. MAX should be used by a licensed health care professional only. Intended for external use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucher for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082218